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Helsinki, 31 October 2022

Addressees
Registrants of JS_6731-36-8 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
18/03/2020

Registered substance subject to this decision ("the Substance")
Substance name: Di-tert-butyl 3,3,5-trimethylcyclohexylidene diperoxide
EC/List number: 229-782-3

Decision number: Please refer to the REACH-IT message which delivered this communication (in format TPE-D-XXXXXXXXXX-XX-XX/F)

DECISION ON TESTING PROPOSAL(S)

Under on Article 40(3)(d) of Regulation (EC) No 1907/2006 (REACH), the testing proposal(s) listed below are rejected:

Testing proposal(s) under Annex IX to REACH

1. Bioaccumulation in aquatic species (OECD TG 305) using the Substance.

Reasons for the rejection are explained in Appendix 1.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Approved[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons for the decision

Contents

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Testing proposal under Annex IX to REACH

1. Bioaccumulation in aquatic species

1 Bioaccumulation in aquatic species is an information requirement under Annex IX to REACH (Section 9.3.2.).

1.1. Information provided

2 You have submitted a testing proposal for Bioaccumulation in Fish: Dietary exposure Test (OECD TG 305-III, dietary exposure) for the Substance.

3 Your dossier already contains information on bioaccumulation in aquatic species:

i. an OECD TG 305 C study performed on *Cyprinus carpio* (1987)
ii. BCF estimations using the QSAR model from Arnot & Gobas (2003)
iii. BCF estimations using the QSAR model from Arnot *et al.* (2008)
iv. In vitro study of S-9 trout metabolism assay (2008)

4 However, you consider the available information as insufficient, for the following reasons:

- Study (i.) does not follow the requirements from the test guideline;
- The QSAR model estimations (ii.) & (iii.) applied for your Substance are not proven as valid; and
- Study (iv.) is not sufficient to fulfil the information requirement.

5 You therefore want to further investigate the Substance by performing a "*reliable Bioaccumulation test on Fish as per OECD TG 305-III (dietary route)*".

ECHA received third party information concerning the testing proposal during the third-party consultation. Comments were received with regard the PBT/vPvB assessment for the Substance. In particular, it was stated that completion of the assessment of persistency should be conducted prior to any further in vivo study to confirm bioaccumulation. The comments are further addressed under section 1.2. below.

1.2. Assessment of the information provided

6 ECHA considers that a bioaccumulation study is not necessary at this stage due to the reasons below.

7 As regards the third party comments, we note that persistency was already addressed under a past substance evaluation decision on the Substance, where was already required. The data generated is currently under evaluation. Besides this assessment, ECHA notes that Bioaccumulation in aquatic species is a standard information requirement under Section 9.3.2. of Annex IX to REACH, which is required for the dossier, irrespective of the PBT assessment.

8 In the context of the previous substance evaluation decision[2], ECHA stated the following:

9 "*The bioconcentration study* [i.e., study i. above] *was carried out based on a generally accepted testing protocol and at two different test concentrations. The higher test*

[2] Substance Evaluation Decision: https://echa.europa.eu/documents/10162/f205b915-5ae7-6190-83c1-4df83a4dc2ef

concentration (0.2 mg/L) is above the recently established water solubility of 93 µg/L and hence, the respective results are not valid.

10 *The lower test concentration (0.02 mg/L) is below the recently derived water solubility of 93 µg/L and therefore, the respective experimental BCF value is considered reliable. The test with the lower test concentration provides a steady state BCF of 5465 L/kg. Therefore, ECHA considers that the available information is sufficient to assess if the Substance meets the B (BCF > 2000) and vB criteria (BCF > 5000) of Annex XIII.*

11 *In your comments* [to the draft Substance evaluation decision], *you refer to a review of the existing bioaccumulation study outlining deficiencies of this study. The available study as well as the submitted review were taken into account in the bioaccumulation assessment by the evaluating MSCA. As explained above, ECHA considers that no further information is needed to assess if the Substance meets the B/vB criteria of Annex XIII. This regulatory assessment is not within the scope of the current decision, but would take place in the process of the identification as a substance of very high concern (SVHC) under Article 59 of REACH, if any*".

12 On this basis, ECHA disagrees with your testing proposal as the information currently available for the Substance (including the in vivo bioaccumulation study in fish) have already been considered and it was concluded that there is no need for further bioaccumulation testing.

13 Therefore, ECHA does not consider your testing proposal as substantiated nor justified or needed.

1.3. Outcome

14 Under Article 40(3)(d) of REACH, the proposed test is rejected.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).
Guidance for monomers and polymers; ECHA (2012).
Guidance on intermediates; ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017).
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs; ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

The Substance was listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2018, and underwent substance evaluation decision with final decision sent on 18 June 2021 requesting further information to clarify a concern relating to persistency of the Substance.

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 5 June 2019. However, as notified to you on 22 April 2020, the testing proposal process was suspended to await the adoption of the substance evaluation decision. The testing proposal process resumed on 18 March 2022.

ECHA held a third party consultation for the testing proposal from 25 June 2019 until 09 August 2019 and from 1 April 2022 until 16 May 2022. ECHA received information from third parties (see Appendix 1).

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

ECHA notified you of the draft decision and invited you to provide comments.

ECHA did not receive any comments within the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix 3: Addressees of this decision

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.